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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,406	02/09/2004	David J. Burke	034008-003	6608

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/773,406	BURKE ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,15-17,23,29-32,41 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,15-17,23,29-32,41,43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5, 7-12, 15-17, 23, 29-32, 41 and 43-45 are pending and are under consideration in the instant application.

2. In light of Applicants' amendment to the claims filed on 5/20/08, the rejection under the 35 U.S.C. 112, first paragraph (sections 4-5 of the action mailed 11/20/07) has been withdrawn. The following rejection remains.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 7-12, 15-17, 23, 29-32, 41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6, 914,128 B1, of record, in view of Gordon et al. (Gastroenterology, 2001, 121:268-274, of record) for the reasons set forth in the office action mailed 11/20/07.

Applicants' arguments filed on 5/20/08 and the declaration by D. Burke on 11/21/07 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the conditions and data disclosed by the‘128 patent cannot be extrapolated to another monoclonal antibody because of the specificity and efficacy of the monoclonal antibody. The declaration by D. Burke states that each antibody must be treated as a new chemical entity because of the structural difference and each antibody formulation must be tailed to the antibody. Moreover, the declaration by D. Burke states the '128 patent discloses a broad ingredients and does not provide any real benefit to those skilled in the art. Therefore, an ordinary skilled in art would not have an expectation of success with the formulation of the ‘128 patent.

Applicants further traversed the rejection based on that the substitution of an antibody formulation with other buffer because of antibodies differ with its specificity and highly relevant to their behavior and efficacy in a formulation. Applicants further argued that the claimed antibody is IgG4 while the referenced antibody IgG1.

However, as taught in the ‘128 patent, the referenced stabilizing formulation is suitable to enhance the shelf life or effectiveness of the antibody formulation for various molecular targets which are structurally unrelated (col. 72-76, in particular) including cell surface molecules designated CD’s, cytokines, growth factors, receptors and its ligands as well as enzyme inhibitors. The ‘128 patent also allows the combination of target molecules (col. 77-78, in particular). Moreover, the ‘128 patent teaches that the expression of antibody (col. 68, lines 29-45) encompasses both IgG1 and IgG4 and the formulation disclosed is suitable to stabilize IgG4 as well.

Unlike Applicants assertion that the ‘128 patent disclose a broad range of ingredients, the ‘128 patent discloses 4 choices of buffers that are well known in the antibody formulation art, histidine, sodium succinate, citrate and phosphate.

As cell surface molecules are considered integrin, and the referenced formulation is suitable for antibodies to other cell surface molecules, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the antibody in the formulation taught by the ‘128 patent with the natalizumab antibody as taught by Gordon et al. Therefore, one of the ordinary skill in the art would have had an reasonable expectation of success. It is reminded that the obviousness rejection does not require absolute predictability but only the reasonable expectation of success. MPEP 2143.02.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody formulation taught by the '128 patent can be used for enhancing shelf life and effectiveness of antibody formulation. As the formulation stabilizes any antibody, it is expected that the antibody formulation taught by the '128 patent would stabilize the natalizumab taught by Gordon et al. as well.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the combination of the references remains obvious.

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
August 25, 2008

/ILIA OUSPENSKI, Ph.D./
Primary Examiner, Art Unit 1644